UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Elizabeth Kane, *as administrator of the estate of William Kane, deceased*, and Elizabeth Kane, *individually*, Plaintiff, -v- Covidien LP, Covidien Sales LLC, Covidien Holding Inc., and Medtronic, Inc. Defendants.	2:23-cv-9207 (NJC) (ARL)

MEMORANDUM AND ORDER

NUSRAT J. CHOUDHURY, United States District Judge:

Plaintiff Elizabeth Kane ("Kane") initiated this action against Covidien LP, Covidien Sales LLC, Covidien Holding Inc., and Medtronic, Inc. (together, "Defendants") on December 15, 2023, bringing New York tort law claims arising out of her husband William Kane's death following three abdominal surgeries. (Am. Compl., ECF No. 16 at 1–20.) On behalf of William Kane, Kane brings a breach of implied warranty claim, as well as design defect, manufacturing defect, and failure to warn products liability claims under strict liability and negligence theories. (Am. Compl. ¶¶ 17–67.) On behalf of herself, Kane brings derivative loss of consortium and wrongful death claims. (*Id.* ¶¶ 68–75.)

Before the Court is Defendants' motion to dismiss the Amended Complaint in its entirety ("Motion"). (Mot. Dismiss, ECF No. 22.) For the following reasons, the Motion is granted in part and denied in part. I grant the Motion with respect to Kane's breach of implied warranty, design defect, and manufacturing defect claims, and dismiss those claims with prejudice. I deny

the Motion with respect to Kane's failure to warn and derivative loss of consortium and wrongful death claims.

BACKGROUND

The following facts are taken from Kane's Amended Complaint and the surgeon's report detailing William Kane's September 16, 2021 operation ("Operative Report"), which is attached to, and incorporated by reference in, the Amended Complaint.[1] (*See generally* Am. Compl.; Operative Report, Am. Compl. Ex. A, ECF No. 16 at 21–24.)

Kane is a New York citizen who resides in Centerreach, New York. (Am. Compl. ¶ 5.) Her husband, William Kane, passed away on December 16, 2021. (*Id.* ¶¶ 6, 69.) On August 30, 2022, Kane was appointed the administrator of William Kane's estate. (*Id*. ¶ 6.)

Covidien LP is a Delaware limited partnership, and its sole general partner is Covidien Holding Inc., a Delaware corporation. (*Id.* ¶¶ 7–8; Defs.' Corrected Corporate Disclosure Statement at 1, ECF No. 28.)[2] Covidien LP, Covidien Holding, Inc., and Covidien Sales LLC are collectively referred to as "Covidien." Medtronic, Inc. is a Minnesota corporation with its principal place of business in Minnesota. (*Id* ¶ 10.)

Collectively, Defendants are "involved in the design, testing, manufacture, distribution, sales, marketing, regulatory management, and services" related to Defendants' surgical stapler products. (*Id.* ¶¶ 7–10.) Relevant here, Kane alleges that Defendants made and sold a set of three

[1] Under the Second Circuit's decision in *Clark v. Hanley*, I consider documents that are incorporated by reference in the Amended Complaint, integral to the Amended Complaint, or otherwise the subject of judicial notice. 89 F.4th 78, 93 (2d Cir. 2023).

[2] Covidien LP has four limited partners: (1) Batts, Inc.; (2) Life Design Systems, Inc.; (3) MSCH LLC, whose sole member is Mallinckrodt US LLC, whose sole member is Mallinckodt, Inc.; and (4) Nellcor Puritan Bennett LLC, whose only member is United States Surgical Corporation. (Defs.' Corrected Corporate Disclosure Statement at 2.) Covidien LP is the sole member of Covidien Sales LLC. (Am. Compl. ¶ 7.)

products used for stapling internal human organs during surgery: (1) "Staple loading unit DST Series GIA Titanium Staples, Blue Cartridge, Size 3.8mm, #GIA6038L"; (2) "Reloadable Stapler, 60mm size, 3.8 open x 1.5mm closed height, Blue, Titanium staples, #GIA6038S"; and (3) "Medtronic TA 60-3.5mm reloadable open stapler, #TA6035S" (together, the "Surgical Stapler").[3] (*Id.* ¶¶ 20–21.)

On September 3, 2021 William Kane underwent a "small bowel resection, mesh removal and primary abdominal wall closure" surgery to treat an "infected recurrent incisional hernia." (Operative Report at 357.) On September 11, 2021, William Kane went to the Stony Brook University Hospital emergency room because he was experiencing "nausea, vomiting and abdominal distension." (*Id.*) Medical staff at the hospital determined that his incisional hernia had recurred, and the next day, on September 12, 2021, he underwent a second surgery. (*Id.*; Am. Compl. ¶ 22.) The Amended Complaint describes the September 12, 2021 surgery as "open repair of incarcerated recurrent incisional hernia with biologic mesh, small bowel resection and primary side to side anastomosis" (Am. Compl. ¶ 22), and the Operative Report describes it as an "exploratory laparotomoy, small bowel resection and abdominal wound closures with biological mesh." (Operative Report at 357.) Michael Paccione, M.D. ("Dr. Paccione") performed the surgery. (*Id.*; Am. Compl ¶ 22.) While the Amended Complaint provides few details on the procedures used to conduct the surgery, it alleges that the surgery involved Dr. Paccione using the Surgical Stapler to seal William Kane's small bowel. (Am. Compl. ¶ 22.)

[3] The Amended Complaint does not clarify whether all or some subset of these three stapler products were used in William Kane's September 12, 2021 surgery. (*See* Am. Compl. ¶ 1 (referring to "a defective surgical stapler"); *id.* ¶¶ 7–8, 10 (referring to multiple "surgical staplers at issue in this case"); *id.* ¶ 40 (referring to a "surgical stapler system").) For simplicity, I refer to these products collectively as the "Surgical Stapler."

Following the September 12, 2021 surgery, William Kane experienced "persistent leukocytosis," and a "CT scan of [his] abdomen . . . revealed pneumoperitoneum with a significant amount of ascites." (*Id.*) As a result of these post-operative complications, on September 16, 2021, Dr. Paccione performed an "exploratory laparotomy with lysis of adhesions, small bowel resection with primary anastomosis and diverting loop ileostomy." (*Id.*; Operative Report at 357–58.) Based on his findings during the September 16, 2021 surgery, Dr. Paccione concluded that the Surgical Stapler had failed to fully seal the surgery site following the September 12, 2021 surgery, causing William Kane's small bowel to leak. (Am. Compl. ¶ 22; *see also* Operative Report at 358.) Specifically, he reported the following findings:

> The small bowel was then identified and eviscerated and run in its entirety to reveal an intact initial anastomosis placed on 9/3/21 approximately 10 cm proximal to the ileocecal value and the second anastomosis that was placed on 9/12/21 had anastomotic leak along the staple line with sucuss entericus leaking from the small bowel dehiscence. . . . The small bowel was run in its entirety and a significant amount of serositis was noted just proximal to the small bowel resection site. <u>The free-end of the small bowel staple line was noted to have a leakage along the new staple line consistent with a failed staple line</u>.

(Am. Compl. ¶ 22 (quoting Operative Report at 358 (emphasis supplied in Amended Complaint).) According to the Amended Complaint, because "a stapling device can compress delicate organ tissue so tightly," a surgeon is often not able to know "whether the stapler properly sealed a stomach, or a staple line failure has occurred" until "several days" after surgery. (*Id.* ¶ 4.) Dr. Paccione reported the failure to a "Stryker Drug Representative," who was apparently present in the operating room at the September 16, 2021 surgery, although the reason for the drug representative's presence is not clear from the pleadings. (Operative Report at 358.)

William Kane died on December 16, 2021. (Am. Compl. ¶¶ 6, 73.) The Amended Complaint does not allege facts concerning the cause of William Kane's death or what occurred between the September 16, 2021 surgery and his death three months later—only that "William

Kane died . . . as a result of the carelessness, recklessness, unskillfulness, manufacturing defect, and/or negligence of Defendants, and/or their employees, without any act, omission to act, or negligent act on the part of the decedent contributing hereto." (*Id.* ¶ 73.)

The Amended Complaint alleges that Defendants "knew[] or should have known" about certain statistics concerning surgical stapler malfunctions.[4] (*Id.* ¶¶ 35–37.) According to a September 2004 article, "112 deaths, 2,180 injuries, and 22,804 adverse events associated with device malfunction had been reported to the FDA's Manufacture and User Facility Device Experience (MAUDE) database." (*Id.* ¶ 35 (citing S. Lori Brown & Eileen K. Woo, *Surgical Stapler-Associated Fatalities and Adverse Events Reported to the Food and Drug Administration*, 199 J. Am. Coll. Surg. 374 (2004)).) Additionally, "[f]rom January 2006 to January 2016, there was a total of 13,312 repots, with 106 events resulting in death, 3,234 resulting in injury, and 9,972 involving a device malfunction."[5] (*Id.* ¶ 36 (citing MK Riggs et al., *Examining Relationships Between Device Complexity and Failure Modes of Minimally Invasive Surgical Staplers*, 3 Biomedical and Biotechnology Engineering (2017)).) Finally, from January 1, 2011 through December 31, 2018, the FDA "received close to 110,000 reports related to issues with surgical staplers. Of these, 412 were submitted as deaths, 11,181 were submitted as serious injuries, and 98,404 were submitted as malfunctions." (*Id.* ¶ 37 (citing FDA Executive Summary prepared for the May 30, 2019, Meeting of the General and Plastic Surgery Devices Panel: Reclassification of Surgical Staplers for Internal Use).) In October 2021, the FDA

[4] The Amended Complaint does not allege that these publications discuss malfunctions relating to the Surgical Stapler model at issue here, only surgical staplers generally.

[5] Excerpts from the Amended Complaint are reproduced here exactly as they appear in the original. Unless otherwise noted, errors in spelling, punctuation or grammar will not be corrected or highlighted.

reclassified surgical staplers from the category of Class 1 devices, which includes band-aids, to Class 2 devices, which require more stringent pre-market review. (*Id.* ¶ 39.)

The Amended Complaint alleges that Defendants "hid the number of adverse reports and malfunctions" of the Surgical Stapler used in William Kane's surgery by submitting a majority of malfunction reports to the "Alternative Summary Reporting program" ("ASR program"), which is not publicly accessible, rather than the FDA's "Manufacture and User Facility Device Experience" database ("MAUDE database"), which is publicly accessible.[6] (*Id.* ¶¶ 35, 38.) The Amended Complaint also alleges that, had William Kane been "truthfully informed of the risks associated with" the Surgical Stapler, he would have elected to have Dr. Paccione use a different sealing device during the surgery. (*Id.* ¶ 40.) Further, the Amended Complaint pleads that 60 millimeter ("mm") staplers, such as the Surgical Stapler used here, "had a higher propensity for failure" and that using "shorter staple line attachment[s]" such as "30 mm or 45 mm options" would result in a "significant" "safety gain" while "add[ing] to surgical time and minimally to surgical costs." (*Id.* ¶¶ 56–57.)

PROCEDURAL HISTORY

On December 15, 2023, Kane filed the Complaint in this action, bringing claims under New York law for breach of implied warranty, products liability under strict liability and negligence theories, loss of consortium, and wrongful death. (ECF No. 1.) On January 16, 2024, Defendants filed a letter motion requesting a pre-motion conference concerning their anticipated motion to dismiss, and on January 19, 2024, Kane responded. (ECF Nos. 6, 7.) On January 24,

[6] The Amended Complaint does not explain what, exactly, these two databases are. Neither the Amended Complaint nor Kane's briefing identifies what specific reporting requirements apply to surgical stapler malfunctions or the circumstances requiring Defendants to report malfunctions with its Surgical Stapler on the public MAUDE database, as opposed to through the non-public ASR program.

2024, I found that a pre-motion conference was not necessary and ordered a briefing schedule. (ECF No. 8.) Pursuant to that schedule, Defendants served their first motion to dismiss on February 13, 2024. (ECF No. 9.)

Rather than oppose that motion, Kane filed the Amended Complaint on March 11, 2024.[7] (Am. Compl.) On March 18, 2024, Defendants filed a letter motion requesting a pre-motion conference concerning their anticipated motion to dismiss, and Kane responded on March 21, 2024. (ECF Nos. 18, 19.) I again held that a pre-motion conference was not necessary and ordered a briefing schedule. (Elec. Order, Mar. 28, 2024.) On April 18, 2024, Defendants served their Motion on Kane. (ECF No. 21.) On May 30, 2024, the Motion was fully briefed, and the parties filed their motion papers on the docket. (Not. Mot. Dismiss, ECF No. 22; Mem. L. Supp. Defs.' Mot. Dismiss ("Mem."), ECF No. 22-1; Affirm. Opp'n & Mem. Opp'n. ("Opp'n"), ECF No. 23; Reply Mem. L. Supp. Defs.' Mot. Dismiss ("Reply"), ECF No. 24.)

JURISDICTION AND VENUE

In two Electronic Orders, dated July 17, 2024 and February 10, 2025, I previously found that the Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000. Elec. Order, July 17, 2024; Elec. Order, Feb. 10, 2025; *see also* 28 U.S.C. § 1332(a) (granting federal district courts original jurisdiction over "all civil actions where the matter in controversy exceeds the sum or value of $75,000 . . . and is between . . . citizens of different States").

[7] On March 11, 2024, Kane filed the Amended Complaint in this action twice. The first filing includes the Amended Complaint and proposed summons. (Am. Compl., ECF No. 15; Proposed Summons, ECF No. 15-1.) The second filing includes the Amended Complaint and the Operative Report as Exhibit A to the Amended Complaint but omits the proposed summons. (Am. Compl.; Operative Report) The copies of the Amended Complaint filed at ECF Nos. 15 and 16 are identical.

Defendants did not raise personal jurisdiction or insufficient service of process defenses under Rule 12(b)(2) and (b)(5), and such defenses are therefore waived. *See* Fed. R. Civ. P. 12(b) ("A motion asserting [a Rule 12(b)(2) or (b)(5) defense] must be made before pleading if a responsive pleading is allowed."); Fed. R. Civ. P. 12(h)(1)(B) ("A party waives any defense listed in Rule 12(b)(2)–(5) by . . . failing to either: (i) make it by motion under this rule; or (ii) include it in a responsive pleading . . . .").

Venue is proper because Kane alleges that a substantial part of the events alleged occurred at Stony Brook University Hospital, which is located in this judicial district. (Am. Compl. ¶ 22; 28 U.S.C. § 1391(b)(2) (providing that venue is proper in "a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred").

LEGAL STANDARD

A complaint must plead sufficient facts to "state a claim to relief that is plausible on its face." *Green v. Dep't of Educ. of City of New York*, 16 F.4th 1070, 1076–77 (2d Cir. 2021) (quotation marks omitted) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "In determining if a claim is sufficiently plausible to withstand dismissal" under Rule 12(b)(6), a court "accept[s] all factual allegations as true" and "draw[s] all reasonable inferences in favor of the plaintiffs." *Melendez v. City of New York*, 16 F.4th 992, 1010 (2d Cir. 2021) (citation and quotation marks omitted). Nevertheless, a court is "not required to credit conclusory allegations or legal conclusions couched as factual allegations." *Hamilton v. Westchester County*, 3 F.4th 86, 91 (2d Cir. 2021) (quotation marks omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The plausibility standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Id.*; *accord We The Patriots USA, Inc. v. Conn. Off. of Early Childhood Dev.*, 76 F.4th 130, 144 (2d

Cir. 2023). While "detailed factual allegations" are not required, "[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do." *Iqbal*, 556 U.S. at 678 (quotation marks omitted). A complaint fails to state a claim "if it tenders naked assertions devoid of further factual enhancement." *Id.* (quotation marks and alterations omitted).

DISCUSSION

Defendants move to dismiss all five claims brought in the Amended Complaint. (*See* Mem.) Concerning Kane's products liability claims, which are brought under both strict liability and negligence—claims under design defect, manufacturing defect, and failure to warn theories—Defendants argue that the Amended Complaint fails to provide non-conclusory factual allegations supporting a claim under any theory. (*Id.* at 6–9.) First, as to the design defect claim, Defendants note that the Amended Complaint does not allege any specific defect, instead only generally alleging that the Surgical Stapler was "improperly designed." (*Id.* at 7 (citing Am. Compl. ¶¶ 32–33, 55).) They also argue that the Amended Complaint does not plead a reasonable alternative design, but rather offers conjecture that "a shorter staple line" was available and would have been less prone to failure. (*Id.* at 8 (citing Am. Compl. ¶ 57).) Second, as to the manufacturing defect claim, Defendants argue that the Amended Complaint does not plead facts alleging that the specific Surgical Stapler used failed to conform to the manufacturer's specifications. (*Id.* at 10.) Third, as to the failure to warn claim, while the Amended Complaint makes multiple references to an alleged failure to provide "proper" or "adequate" warnings, Defendants contend that it does not provide any factual allegations concerning what warning, if any, Defendants did provide or any factual allegations explaining what would constitute a sufficient warning in this situation. (*Id.* at 11; *see also* Am. Compl. ¶¶ 32–33, 55, 65.) Defendants also argue that the Amended Complaint does not allege that they failed to warn the *prescribing physician* specifically, as required in a failure to warn case

involving medical treatment. (Mem. at 11.) With respect to all three products liability theories, Defendants argue that the Amended Complaint does not adequately plead that the alleged Surgical Stapler failure was the "but for" cause of William Kane's injury and death, in particular because it does not allege any facts concerning what did cause William Kane's death, much less facts supporting a plausible claim that the Surgical Stapler failure caused it. (*Id.* at 9.)

Concerning Kane's breach of implied warranty claim, Defendants argue that the Amended Complaint lacks sufficient "factual specificity" to sustain this claim under New York law. According to Defendants, the only fact alleged in the Amended Complaint supporting the Surgical Stapler failure is the Operative Report from the September 16, 2021 surgery, in which Dr. Paccione concluded that there was a "failure to the stapler device" during the September 12, 2021 surgery. (*Id*. at 5 (citing Operative Report at 357–58).) They argue that this single fact is insufficient to establish that the Surgical Stapler failed, because, as they claim, it is not clear from the Amended Complaint whether Dr. Paccione was even present for the September 12, 2021 surgery. (*Id.* at 6.) Defendants also point out that the Amended Complaint does not allege that the hospital staff documented the supposed Surgical Stapler failure, reported the failure to the FDA (as required by 21 C.F.R. § 803.1), or inspected the specific Surgical Stapler unit used in the September 12, 2021 surgery. (*Id.*) Finally, Defendants suggest that the Surgical Stapler used might not have been its product, noting that the Operative Report states that Dr. Paccione reported the malfunction to a representative from "Stryker," a different medical device manufacturing company. (*Id.*)

Concerning Kane's claims for loss of consortium and wrongful death, Defendants argue that Kane can only maintain these claims if the products liability and breach of implied warranty

claims go forward; accordingly, if I dismiss those primary claims, I must also dismiss these derivative claims. (*Id.* at 11–12.)

In opposition, Kane maintains that the allegations in the Amended Complaint are sufficient to sustain her primary claims on behalf of William Kane. (Opp'n ¶¶ 9–22.) Kane argues that the following allegations in the Amended Complaint support the "reasonable inference" that the Surgical Stapler used during the September 12, 2021 surgery did not work for its intended purpose: (1) that William Kane experienced small bowel leakage following the September 12, 2021 surgery, in which Dr. Paccione removed a portion of his small bowel, and (2) that, based upon the exploratory surgery on September 16, 2021, Dr. Paccione concluded that "a failure to the stapler device" caused the leakage. (*Id.* ¶¶ 11, 17.) Kane asserts that Defendants' arguments for dismissal raise factual disputes inappropriate for resolution on a Rule 12(b)(6) motion to dismiss, where the Court must take all well-pled allegations as true. (*Id.* ¶¶ 13, 15.) In particular, she argues that whether hospital personnel reported the Surgical Stapler defect and whether Dr. Paccione had sufficient personal knowledge to conclude that William Kane's bowel leak was caused by the Surgical Stapler failure are fact questions to be developed during discovery. (*Id.* ¶¶ 13, 15). On this point, Kane also points out that the Operative Report, incorporated by reference into the Amended Complaint, not only indicates that Dr. Paccione was present at the September 12, 2021 surgery, but that he was, in fact, the surgeon who performed that surgery. (*Id.* ¶ 14 (citing Operative Report at 359).)

Regarding the products liability claims, Kane argues that the Amended Complaint plausibly alleges liability under all three theories. As to design defect, Kane claims that the Amended Complaint alleges a safer alternative design by referencing the availability of 30 mm and 45 mm stapler models. (*Id.* ¶ 22.) As to manufacturing defect, Kane submits that the Court

can infer a manufacturing defect based on the allegation that Dr. Paccione concluded that a stapler failure caused the leakage that led to the September 16, 2021 surgery. (*Id.* ¶ 19 (citing Am. Compl. ¶ 22).) As to failure to warn, Kane cites the following allegations: (1) that Defendants hid the frequency of surgical stapler failures by reporting them through the FDA's non-public ASR program rather than the public MAUDE database; (2) that Defendants did not adequately instruct users within the medical community that stapler height should be chosen in light of the thickness of the tissue being stapled; and (3) that Defendants knew, but hid from physicians, that the 60 mm Surgical Stapler had a "higher propensity for failure" than other versions. (*Id.* ¶ 21 (citing Am. Compl. ¶¶ 35–38, 41, 56.)

Kane does not specifically respond to Defendants' arguments as to her loss of consortium and wrongful death claims, and thus concedes that if I dismiss her primary claims on behalf of William Kane, I must also dismiss her derivative claims.

For the reasons that follow, the Amended Complaint fails to plausibly allege design defect, manufacturing defect, and breach of implied warranty claims, but does plausibly allege failure to warn, loss of consortium, and wrongful death claims.

I. Products Liability (Strict Liability and Negligence)

As discussed, Kane brings products liability claims under both strict liability and negligence under three different theories—design defect, manufacturing defect, and failure to warn. "New York courts generally consider strict products liability and negligence claims to be functionally synonymous." *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 406 (S.D.N.Y. 2013); *see also Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001) (holding that design defect strict liability and negligence claims are "virtually identical"); *Rosen v. St. Jude Medical, Inc.*, 41 F. Supp. 3d 170, 182 (N.D.N.Y. 2014) (applying same standard for analyzing manufacturing defect claims under strict liability and negligence); *Estrada v. Berkel*

Inc., 789 N.Y.S.2d 172, 172 (N.Y. App. Div. 2005) (holding that failure to warn claims under strict liability and negligence are "equivalent"). Accordingly, I analyze these two claims together.

Under New York law, a plaintiff may bring a products liability claim under the theories of design defect, manufacturing defect, and failure to warn. *Hayes v. Smith & Wesson*, 692 F. App'x 70, 71 (2d Cir. 2017) (summary order citing *McCarthy v. Olin Corp.*, 119 F.3d 148, 154–55 (2d Cir. 1997)). I address each in turn.

A. Design Defect

To state a design defect claim, the plaintiff must plead facts sufficient to establish that: "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." *Colon ex re. Molina,* 199 F. Supp. 2d at 83; *see also Hoover v. New Holland North America, Inc.*, 988 N.Y.S.2d 543, 551 (2014) (holding that the plaintiff must show that the defendant "breached its duty to market safe products when it marketed a product designed so that it was not reasonably safe and that the defective design was a substantial factor in causing plaintiff[']s injury"). "A defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use, and whose utility does not outweigh the danger inherent in its introduction into the stream of commerce." *Hoover*, 988 N.Y.S.2d at 551 (quotation marks omitted). A design defect claim is subject to dismissal where the plaintiff fails to "allege with sufficient specificity how the design . . . [is] defective" or identify the "existence of a feasible alternative design." *Tears v. Boston Scientific Corp.*, 344 F. Supp. 3d 500, 509

(S.D.N.Y. 2018) (citations and quotations omitted). Here, the Amended Complaint fails to satisfy any of the three elements required to state a claim for design defect.

First, the Amended Complaint does not identify any specific defect in the Surgical Stapler's design that poses a "substantial likelihood of harm." *Colon ex re. Molina,* 199 F. Supp. 2d at 83. In her Opposition, Kane points to statistics provided in the Amended Complaint concerning aggregate numbers of reported malfunctions and injuries related to surgical stapling devices in general. (Opp'n ¶ 18 (citing Am. Compl. ¶¶ 35–38).) Kane did not attach to the Amended Complaint copies of the cited reports. Based on the Amended Complaint's description, however, the statistics referenced appear to concern surgical stapling devices generally, not necessarily the specific Surgical Stapler at issue here. Moreover, the Amended Complaint's allegation that 60 mm staplers have "a higher propensity for failure" is insufficient to establish that the Surgical Stapler's 60 mm specification is an "unreasonably dangerous" design defect as opposed to a necessary feature for serving its function. *See* Am. Compl. ¶ 56–57; *see also Goldin v. Smith & Nephew, Inc.*, No. 12-cv-9217, 2013 WL 1759575, at *4 (S.D.N.Y. Apr. 24, 2013) (dismissing design defect claim where plaintiff "state[d] that the product poses a risk of harm because of its propensity to dislocate, but d[id] not identify any particular problem in the design of the product").

Second, and relatedly, the Amended Complaint's allegation that 30 mm and 45 mm stapling devices exist does not establish that such devices would be a "reasonable alternative design." (*See* Am. Compl. ¶ 57.) As the Amended Complaint notes, "choosing a staple height that is incompatible with a specific tissue's thickness and biochemical properties can lead to improper sta[p]le formation, resulting in leaks, tissue damage and other complications." (Am. Compl. ¶ 41.) The Amended Complaint does not address what range of "staple height[s]" would

be compatible with stapling small bowel tissue, as was done during William Kane's September 12, 2021 surgery. In other words, it does not plead facts showing that 30 mm or 45 mm stapling devices would be reasonable alternative designs for use in the type of small bowel resection surgery performed on William Kane. *Cf. SUEZ Water N.Y. Inc. v. E.I. du Pont de Nemours and Co.*, 578 F. Supp. 3d 511, 561 (S.D.N.Y. 2022) (collecting cases in which courts have held that complaints failed to allege a reasonable alternative design with sufficient specificity).

Third, having failed to allege a specific design defect, the Amended Complaint also fails to plausibly allege that any such defect was a substantial factor in causing William Kane's injury and death. In opposition, Kane points to Dr. Paccione's conclusion in the Operative Report that there was leakage at the staple line of the small bowel and that a stapler failure occurred shortly after the Surgical Stapler was used during the September 12, 2021 surgery, arguing that these alleged facts "allow[] the court to draw the reasonable inference that defendants are liable." (Opp'n ¶ 11.) Kane casts Defendants' argument that Dr. Paccione does not have the requisite personal knowledge to conclude what caused William Kane's injury and death as attacks on Dr. Paccione's credibility that are not appropriate at this stage, where the Court must accept as true all well-pled allegations in the Amended Complaint. (Opp'n ¶ 13 (citing *Presley v. City of Charlottesville*, 464 F.3d 480, 483 (4th Cir. 2006)).)[8] While Kane is correct that I must take the Amended Complaint's allegations as true, Dr. Paccione's conclusion in the Operative Report does not plead a sufficient causal link between any alleged defect and any alleged harm. While

[8] Kane also cites *Presley* for the proposition that "a Rule 12(b)(6) motion should not be granted unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." 464 F.3d at 483. In addition to being an out-of-circuit decision that is not binding authority, this case is not good law because it was decided in 2006, before the Supreme Court set forth the plausibility standard in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

these two allegations may be enough for me to draw a "reasonable inference" that William Kane's small bowel leak necessitating the September 16, 2021 surgery was caused by the failure of the Surgical Stapler used during the September 12, 2021 surgery, they do not establish that a *design defect* caused the Surgical Stapler failure.[9] Moreover, as Defendants point out, the Amended Complaint contains no factual allegations concerning William Kane's cause of death on December 16, 2021, other than that it occurred approximately three months after the September 12, 2021 surgery. (*See* Mem. at 9.) Having failed to plead any factual allegations concerning the cause of the Surgical Stapler failure and the death of William Kane, all that is left in the Amended Complaint is the conclusory allegation that "William Kane died . . . as a result of the carelessness, recklessness, unskillfulness, manufacturing defect, and/or negligence of Defendants." (Am. Compl. ¶ 73.) This is not sufficient to state a claim for design defect.

B. Manufacturing Defect

While a design defect arises when a product is manufactured adequately pursuant to its defective design, a manufacturing defect arises when an adequately designed product is manufactured in a manner that fails to meet its design specifications. *Tears*, 344 F. Supp. 3d at 510. "To successfully plead a manufacturing defect claim, the complaint must allege both that a specific product unit was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction, and that the defect was the cause of plaintiff's injury." *Id.* (quotation marks omitted). The plaintiff may

[9] Defendants also raise the possibility that Dr. Paccione might have used a different brand of surgical stapling device altogether, noting that the Operative Report indicates that he reported the suspected failure to a representative for "Stryker," not Covidien or Medtronic. (Mem. at 3 (citing Operative Report at 358).) This may or may not be the case, but on the 12(b)(6) motion before me, I take as true the Amended Complaint's allegation that Dr. Paccione used the Defendants' Surgical Stapler in the September 12, 2021 procedure. (*See* Am. Compl. ¶ 22.)

allege a manufacturing defect by circumstantial evidence where the specific product at issue is not available for inspection. *Speller ex rel. Miller v. Sears, Roebuck & Co.*, 100 N.Y.2d 38, 41 (2003). If the plaintiff cannot identify a specific manufacturing defect, then it must "prove that the product did not perform as intended and exclude all other causes for the product's failure that are not attributable to defendants." *Id.*

Here, too, the Amended Complaint fails to plausibly allege the elements of a manufacturing defect claim. The Amended Complaint's sole factual allegation concerning a manufacturing defect is Dr. Paccione's conclusion that a staple failure caused William Kane's small bowel to leak. (*See* Opp'n ¶ 19 (citing Am. Compl. ¶ 22).) Again, while this allegation may be enough to plead that the Surgical Stapler failed, it does not plausibly allege a defect in the manufacturing of the Surgical Stapler. Kane cites to *Williamson v. Stryker Corp.*, No. 12-cv-7083, 2013 WL 3833081, at *5 (S.D.N.Y. July 23, 2013) for the proposition that manufacturing defects can be shown through circumstantial evidence. (Opp'n ¶ 11.) *Williamson* is distinguishable, however, because, in that case, "the possibility of other causes ha[d] been excluded." *Williamson*, 2013 WL 3833081, at *5. The Amended Complaint does not allege that all potential causes of the Surgical Stapler's failure other than manufacturing defect, such as, for example, user error, have been eliminated. Further, as addressed in Discussion Section I.A. above, absent any allegations concerning the cause of William Kane's death more than three months after the September 12, 2021 surgery during which the Surgical Stapler failure was alleged to have occurred, the Amended Complaint fails to plead that a manufacturing defect caused William Kane's death.

C. Failure to Warn

To state a claim for failure to warn, "a plaintiff must demonstrate (1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." *State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 F. App'x 8, 10 (2d Cir. 2011) (summary order citing *Liriano v. Hobart Corp.,* 92 N.Y.2d 232, 237 (1998)). "When the product at issue is a medical device, the manufacturer's duty to warn applies to the physician as a 'learned intermediary' rather than to the patient himself." *Tears*, 344 F. Supp. 3d at 511 (citing *Banker v. Hoehn*, N.Y.S.2d 438, 440 (2000) ("The manufacturer of the medical device satisfies its duty to warn of potential adverse effects when it adequately warns medical professionals who use the device in the treatment of patients.")).

Unlike her manufacturing defect and design defect claims, Kane's failure to warn claim is supported by factual allegations in the Amended Complaint. First, the Amended Complaint alleges that Defendants provided surgeons "very little guidance" concerning how to select the stapler height most appropriate for use based on tissue thickness and other factors. (Am. Compl. ¶ 41.) Second, the Amended Complaint alleges that the 60 mm Surgical Stapler model (the model allegedly used on William Kane) had a "higher propensity for failure" than the 30 mm and 45 mm models, that Defendants knew this fact, and that they failed to provide surgeons warnings that they should employ "additional means of reinforcement" when using the 60 mm model or "at least closely and carefully inspect the area" on which it was used. (*Id.* ¶ 56.) Third, the Amended Complaint alleges that Defendants kept "hidden from surgeons and their patients" risks associated with the Surgical Stapler by filing a majority of incidents identified with its surgical stapling products through the non-public ASR program rather than the FDA's public

MAUDE database, which purportedly had the effect of concealing from healthcare providers the full extent of the Surgical Stapler's failure rate. (*Id.* ¶ 38.) Fourth, as to causation, the Amended Complaint alleges that "[h]ad [William Kane] and/or his clinicians been truthfully informed of the risks associated with the relevant surgical stapler system used during [William Kane's] surgical procedure, [William Kane] and/or [his] clinicians would not have used the device during the surgery." (*Id.* ¶ 40.) Accordingly, Kane has plausibly alleged that Defendants failed to warn the prescribing physician (here, Dr. Paccione), and that this failure caused at least some injury to William Kane (e.g., William Kane's small bowel leak and need for additional surgery).

Defendants' arguments in opposition are unpersuasive. Defendants' claim that the Amended Complaint fails to allege "what warnings would have been adequate" is inaccurate, since, as noted above, the Amended Complaint specifically pleads that Defendants should have informed surgeons (1) which stapler heights were appropriate for certain procedures and (2) that the 60 mm Surgical Stapler model had a higher failure rate and, accordingly, surgeons using this model should either add reinforcements or closely inspect the surgery site for leaks. (Mem. at 11; Am. Compl. ¶¶ 41, 56.) Defendants' argument that the Amended Complaint does not allege that they failed to warn the "prescribing physician" is similarly unavailing because, as noted above, the Amended Complaint does make such an allegation. (Mem. at 11; Am. Compl. ¶¶ 41, 56.) On this point, Defendants' claim that the Amended Complaint does not plead the identity of the surgeon who performed the September 12, 2021 surgery is incorrect, since the Operative Report attached to the Amended Complaint states that Dr. Paccione performed both the September 12, 2021 and September 16, 2021 surgeries. (Mem. at 11; Operative Report at 359.)

II. Breach of Implied Warranty

New York law adopts the Uniform Commercial Code's ("UCC") implied warranty of merchantability. UCC § 2-314; *see also Saratoga Spa & Bath, Inc. v. Beeche Sys. Corp.*, 656

N.Y.S.2d 787, 790 (1997) (New York Court of Appeals applying UCC § 2-314). Under this implied warranty provision, goods must be "reasonably fit for their intended purpose." *Saratoga Spa & Bath*, 656 N.Y.S.2d at 790. "To state a claim for a breach of the implied warranty of merchantability [under New York law], plaintiff must allege that the product was defectively designed or manufactured, that the defect existed when the manufacturer delivered the product to the purchaser, and that the defect is the proximate cause of the plaintiff's injury." *Tears*, 344 F. Supp. 3d at 513. Accordingly, "[t]he facts required to demonstrate a breach of the implied warranty of merchantability are thus very similar as those needed to support a strict products liability claim." *Id.* Notably, however, a breach of implied warranty claim does not require a showing of a reasonable alternative design. *See Bah v. Nordson Corp.*, No. 00-cv-9060, 2005 WL 1813023, at *13 (S.D.N.Y. Aug. 1, 2005).

For the reasons described above regarding Kane's design defect and manufacturing defect claims, the Amended Complaint likewise does not plausibly allege a breach of implied warranty claim. Though the Amended Complaint alleges that the Surgical Stapler is "an inherently and unreasonably dangerous product when used in the ordinary and usual manner," it does not support this legal conclusion with sufficient factual allegations. (Am. Compl. ¶ 65.) In particular, the Amended Complaint does not allege a specific design or manufacturing defect, nor does it plausibly allege that such defect caused William Kane's post-surgery complications and death.

III. Derivative Claims

Defendants' only argument supporting dismissal of Kane's loss of consortium and wrongful death claims is that they are derivative claims that cannot proceed if Kane's primary products liability and failure to warn claims are dismissed. Mem. at 11–12; *Nealy v. U.S. Surgical Corp.*, 587 F. Supp. 2d 579, 585–86 (S.D.N.Y. 2008) ("Under New York law, a claim

for loss of companionship . . . is derivative of the related primary causes of action; dismissal of the primary claims requires the Court to dismiss any dependent derivative claims . . . . Similarly, . . . the viability of a survival claim is dependent upon the viability of the underlying personal injury claim.") (citations omitted). Because the Amended Complaint pleads a plausible failure to warn claim, Kane's loss of consortium and wrongful death claims can proceed as derivative of this claim.

CONCLUSION

For the reasons set forth above, Defendants' Motion to Dismiss Kane's Amended Complaint is granted in part and denied in part. (ECF No. 22.) The Court dismisses Kane's design defect, manufacturing defect, and breach of implied warranty claims with prejudice. Kane's failure to warn, loss of consortium, and wrongful death claims may proceed in this action.

Dated: Central Islip, New York
February 12, 2025

/s/ Nusrat J. Choudhury
NUSRAT J. CHOUDHURY
United States District Judge